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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,878	09/08/2003	Mark W. Kroll	A03P1062US04	2626

36802 7590 03/03/2006

PACESETTER, INC.
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EXAMINER	
MALAMUD, DEBORAH LESLIE	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/657,878	KROLL ET AL.	
	Examiner	Art Unit	
	Deborah Malamud	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 September 2003* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/8/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4-7 of copending Application No. 10/657,858. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications teach a pacing unit for delivering primary pacing pulses, a pulse capture detection unit and a capture-based tachycardia detection unit operative to detect a tachycardia based on loss of capture.

3. Claims 8-11 and 13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-14 and 18 of copending Application No. 10/657,840. Although the conflicting claims are not identical,

they are not patentably distinct from each other because both applications teach a method comprising delivering a primary pacing pulse to the heart, verifying capture of the pacing pulses, delivering a backup pulse and verifying capture of the backup pulses.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

4. Claim 7 is objected to because of the following informalities: in line 2 of the claim "until" should be replaced with "unit." Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Mouchawar et al (U.S. 6,553,259). Mouchawar discloses (column 5, lines 20-24) "an implantable cardiac stimulation device including a method for sensing cardiac events and delivering both high and low voltage stimulation therapies for appropriately treating bradycardia, tachycardia, or fibrillation. One method of therapy delivery includes 1)

sensing for cardiac activity within a cardiac chamber during a defined escape interval; 2) when intrinsic cardiac activity is not detected within the given escape interval, delivering a stimulation pulse for the purpose of stimulating the cardiac chamber to contract at a desired rate; 3) verifying that the delivered stimulation pulse produced an evoked response by sensing during an alert interval following a short refractory period; 4) if no evoked response is detected during the alert interval, sustaining the desired stimulation rate by delivering a back-up stimulation pulse; 5) whenever a back-up stimulation pulse is required, performing a capture search for determining the minimum pulse energy needed to reliably achieve capture, and 6) adjusting the programmed stimulation energy to a level safely above the newly determined capture energy. When the automatic capture function is enabled, the stimulation device initiates a stimulation refractory period, upon the expiration of which, the stimulation device sets a sensing threshold to an evoked response threshold." Mouchawar further discloses (column 4, lines 47-55) "an implantable cardiac stimulation device possessing pacing, cardioversion and defibrillation functions and automatic capture capabilities, for automatically verifying capture during stimulation operations and, as necessary, automatically delivering back-up stimulation pulses when capture is lost, and subsequently adjusting the stimulation energy to a level safely above that needed to achieve capture." See Figures 1 and 2. The examiner considers the system of these figures to be a pacing unit, capture detection unit and capture-based ventricular tachycardia detection unit.

Regarding claim 2, Mouchawar discloses (column 17, line 67; column 18, lines 1-5) "if no evoked response is detected, a back-up stimulation pulse, preferably equal to

1.5 to 2 times the current pulse amplitude, is delivered (at step 527), and the method (500) returns (to step 505) to verify that the pulse width has not reached a maximum, and then continues to increase the pulse energy by incrementing the pulse width (step 515)." The examiner considers this to be an atrial tachycardia detection unit that detects atrial tachycardia based on loss of capture of both an atrial pacing pulse delivered at less than the maximum pulse magnitude and a subsequent backup pulse that is delivered at the maximum pulse magnitude.

Regarding claim 3, Mouchawar discloses (column 18, lines 59-63) "automatic threshold test mode or method (900), is illustrated in the flow of FIG. 13. Automatic threshold testing may be performed upon a programmed command or periodically, such as daily weekly or monthly, or upon an event-trigger from microprocessor (60)." The examiner considers this to teach a stimulation threshold search operative to determine a capture threshold for primary pacing pulses.

Regarding claim 6, Mouchawar discloses (column 5, lines 20-23) "an implantable cardiac stimulation device including a method for sensing cardiac events and delivering both high and low voltage stimulation therapies for appropriately treating bradycardia, tachycardia, or fibrillation."

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 8-9 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Andersson et al (U.S. 5,846,264). Andersson discloses (column 1, lines 40-50) "some

pacemakers have means which not only test for successful capture but also, in the event of loss of capture, are capable of generating a back-up pulse shortly after the failure in order to sense an evoked response from a preceding stimulus. The back-up pulse is supplied from the stimulation circuit, which contains a stimulation capacitor. In order to ensure capture, the energy supplied in the back-up pulse is discharged at the maximum permissible voltage, usually around 4.5 volts. Thus immediately after each stimulation pulse has been discharged, the stimulation capacitor is charged to its maximum voltage of around 4.5 volts, so as to be able to produce a back-up pulse if one is required." Andersson further discloses (column 2, lines 30-40) a pacemaker that "includes an output stage (1) connected to a heart, an evoked response detector (5), also connectable to the heart (2), and a pacing control unit (3) which operates the output stage and the evoked response detector. In one embodiment of the invention, shown in FIG. 1, the output stage of the pacemaker (4) has, in addition to the usual stimulation capacitor (C1) and compensation capacitor (C2), at least one back-up pulse capacitor (C3). In order to stimulate the heart, the stimulation capacitor, which typically has a capacitance of 10 microfarads, is charged by a charge pump to a voltage determined by the physician or the manufacturer, which could be, for example, 1.5 volts. When the pulse is to be sent to the heart, switch (S1) is closed by the pacing control unit and current flows through the output circuit to the heart via the compensation capacitor. Compensation capacitor has a capacitance of typically 5 microfarads, and it is charged by the current passing through it." The examiner considers this to be delivering primary pacing pulses to the ventricles of the heart, verifying capture of the

primary pacing pulses, delivering a backup pulse to the ventricles upon detection of a loss of capture of a primary pacing pulse, verifying capture of the ventricular backup pacing pulse and detecting a ventricular tachycardia based upon detection of loss of capture of a backup pulse in the ventricles. Pulses are delivered at a pulse magnitude less than a predetermined maximum pulse magnitude and the backup pulse is delivered at the maximum pulse magnitude.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 4-5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mouchawar et al (U.S. 6,553,259) in view of Bradley et al (U.S. 2003/0208241). Mouchawar discloses the claimed invention except for activation of the stimulation threshold search unit if a programmable number of consecutive pacing pulses do not capture but corresponding backup pulses do capture. Bradley however discloses (paragraph 0052) "if, however, any of the overdrive pacing pulses are not captured by the atria (i.e. a LOC has been detected) then, following step 204, a backup pacing pulse is delivered at step 210. The backup pulse is set to the HOM voltage of, for example, 4.5V and is delivered 40 ms after the pulse that failed to evoke capture. The Consecutive LOC Counter is incremented at step 211. If the LOC is a first LOC,

processing simply continues at step 202 for further overdrive pacing. However, upon detection of a second consecutive LOC during the dwell time, the overdrive unit performs an automatic capture threshold detection search at step 212 using the technique of FIG. 4 to set a new capture threshold and a new pulse magnitude. Thereafter, the next sequence of overdrive pacing pulses is generated using the new pulse magnitude. Thus two consecutive LOCs trigger a capture threshold detection search. A capture detected subsequent to a first LOC will reset the Consecutive LOC Counter at step 205 so that the next LOC will not immediately trigger the capture threshold detection search." Both Bradley and Mouchawar teach systems that provide overdrive pacing with capture verification. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Mouchawar's overdrive pacing with Bradley's stimulation threshold search if a primary pacing pulse is not captured but a backup pulse is captured in order to ensure that capture of the heart is attained.

Regarding claim 5, Mouchawar discloses (column 19, lines 5-10) "the threshold test mode then progressively decreases the stimulation pulse energy until a threshold test criterion is satisfied (at decision step 910). For example, a specified number of cycles in which the current pulse energy fails to capture the paced chamber, preferably two consecutive capture failures." The examiner considers this to be an atrial stimulation threshold search unit that is activated if a first number of delivered pulses.

Regarding claim 7, the examiner considers the method illustrated in Figure 3 in the Bradley reference to illustrate preventive overdrive pacing. See also paragraph 0052.

11. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersson et al (U.S. 5,846,264) in view of Bradley et al (U.S. 2003/0208241). Andersson discloses the claimed invention except for performing a stimulation threshold search using the stimulation threshold search unit if a primary pacing pulse is not captured but a backup pulse is captured. In paragraph 0052, Bradley discloses performing a stimulation threshold search using the stimulation threshold search unit if a primary pacing pulse is not captured but a backup pulse is captured. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Andersson's overdrive pacing with Bradley's stimulation threshold search if a primary pacing pulse is not captured but a backup pulse is captured in order to ensure that capture of the heart is attained.

Regarding claim 11, the examiner considers the method illustrated in Figure 3 of the Bradley reference to illustrate preventive overdrive pacing. See also paragraph 0052.

12. Claims 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Andersson et al (U.S. 5,846,264) in view of Olson et al (U.S. 6,731,978). Andersson discloses the claimed invention except for delivering shock therapy to the ventricles if both a primary pacing pulse and a backup pulse are not captured in the ventricles. Olson however discloses (column 16, lines 34-48) "the processor determines which of

the various available rules have all of their respective clauses satisfied." If "one, more than one, or no rules may have their causes all satisfied. If more than one rule is true or "fires" the rule of highest priority is selected, leading to a rhythm classification corresponding to that rule. In response to the classification of the rhythm, the device delivers therapy or prevents delivery of therapy, depending upon the rhythm identified. In the absence of any rules being identified, the device withholds anti-tachycardia therapy. If the device is programmed to provide bradycardia backup pacing, it continues to do so. If not, the device simply continues to monitor the rhythm of the heart, until one or more rules fire." Both Andersson and Olson teach treatment of arrhythmias in the heart. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Andersson's overdrive pacing system with Olson's antitachycardia pacing in order pace a heart in the event of loss of capture.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 8.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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